State of Utah
Administrative Rule Analysis

NOTICE OF PROPOSED RULE OR CHANGE

The agency identified below in box 1 provides notice of proposed rule or change pursuant to Utah Code Subsections 63-46a-4(2) and (4). Please address questions regarding information on this notice to the agency. The full text of all rule filings is published in the *Utah State Bulletin* unless excluded because of space constraints. The full text of all rule filings may also be inspected at the Division of Administrative Rules.

State of Utah Division of Administrative Rules (DAR) 4120 State Office Building; 450 North Main PO Box 141007 Salt Lake City, UT 84114-1007 Phone: (801) 538-3218, FAX: (801) 538-1773 State E-mail: *asdomain.asitmain.rules*	DAR file no.:	
	Utah Admin. Code ref. (R no.):	R156-17a-612
	Date filed:	
	Time filed:	
	Received by:	

1.	Department:	Commerce
	Agency:	Occupational and Professional Licensing
	Room no., building:	Heber M. Wells Building - 4th Floor
	Street address:	160 East 300 South
	Mailing address:	PO Box 146741
	City, state ZIP:	Salt Lake City UT 84114-6741
	Contact person:	Diana Baker
	Telephone:	(801) 530-6179
	FAX:	(801) 530-6511
	Internet E-mail:	dbaker@utah.gov

(Interested persons may inspect this filing at the above address or at DAR between 8:00 a.m. and 5:00 p.m. on business days.)

2. Title of rule or section (catchline):

Operating Standards - Pharmaceutical Wholesaler/Distributor and Pharmaceutical Manufacturer located in Utah

3. Type of notice:

Proposed rules		New	X	Amendment		Repeal		
		Repeal and reenact						
Other rule types		Change in proposed rule	(changes original proposed rule file no.:		)			

4. Purpose of the rule or reason for the change:

The Division needs to update the edition of the United States Pharmacopeia/National Formulary (USP/NF) books which are incorporated by reference.

5. This rule or change is a response to comments by the Administrative Rules Review Committee. [ ] Yes [X] No

6. Summary of the rule or change:

In paragraph (7)(a), the USP/NF book is updated to the 2002 edition, which is official from January 1, 2003 through Supplement 2, dated August 1, 2003.

7. Aggregate anticipated cost or savings to:

State budget:	The Division will incur minimal costs, less than $100, to reprint this rule once the proposed amendment is made effective. Any costs incurred will be absorbed in the Division's current budget.
Local government:	Proposed rule does not apply to local governments.

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Other persons:	Pharmaceutical wholesalers/distributors and pharmaceutical manufacturers located in Utah should already have the current edition of the USP/NF book and supplements. However, if they do not have the current edition, a subscription for the book and supplements costs approximately $650.00 every year since the book and supplements are updated on a yearly basis. The Division is unable to determine how many of the wholesalers/distributors or manufacturers do not have the current edition of the book and supplements.

8. Compliance costs for affected persons ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an agency):

Pharmaceutical wholesalers/distributors and pharmaceutical manufacturers located in Utah should already have the current edition of the USP/NF book and supplements. However, if they do not have the current edition, a subscription for the book and supplements costs approximately $650.00 every year since the book and supplements are updated on a yearly basis. The Division is unable to determine how many of the wholesalers/distributors or manufacturers do not have the current edition of the book and supplements.

9. Comments by the department head on the fiscal impact the rule may have on businesses:

No fiscal impact to business is anticipated from this rule filing, which merely amends a reference in the rule to the current edition of the United States Pharmacopeia/National Formulary. Klarice Bachman, Executive Director

10. This rule or change is authorized or mandated by state law, and implements or interprets the following state and federal laws.

State code or constitution citations (required):	Section 58-17a-101 and 58-37-1 and Subsections 58-1-106(1)(a) and 58-1-202(1)(a)
Federal citations (optional):	

11. This rule or change adds or updates an incorporated reference (submit a copy to DAR): [X] Yes [ ] No

Reference title and date of issue or edition:	Deletes 1995 edition of the USP/NF through Supplement 4, dated August 1, 2001 Adds 2002 edition of the USP/NF through Supplement 2, dated August 1, 2003

12. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the *Utah State Bulletin*. See Section 63-46a-5 and Rule R15-1 for more information.)

Comments will be accepted until 5:00 p.m. on (mm/dd/yyyy):	12/15/2003		
A public hearing (optional) will be held on (mm/dd/yyyy):		at (time):	
at (place):			

13. This rule or change may become effective on (mm/dd/yyyy): 12/16/2003

14. Indexing information - keywords (maximum of four, in lower case):

pharmacists, licensing, pharmacies

15. Indexing information - affected industries (two-digit SIC codes):

n/a

16. Attach a WordPerfect document containing the text of this rule or change (filename): R156-17a.pro

To the agency: Information requested on this form is required by Sections 63-46a-4, 5, 6, and 10. Incomplete forms may be returned to the agency for completion, possibly delaying publication in the *Utah State Bulletin*, and delaying the first possible effective date.

AGENCY AUTHORIZATION

Agency head or designee, and title:	J. Craig Jackson, Director	Date (mm/dd/yyyy):	10/23/2003

R156. Commerce, Occupational and Professional Licensing.
R156-17a. Pharmacy Practice Act Rules.
R156-17a-612. Operating Standards - Pharmaceutical Wholesaler/Distributor and Pharmaceutical Manufacturer located in Utah.

In accordance with Subsection 58-17a-601(1), the operating standards for pharmaceutical wholesaler/distributor and pharmaceutical manufacturer licensee includes the following:

(1) A separate license shall be obtained for each separate location engaged in the distribution or manufacturing of prescription drugs.

(2) A separate license shall be obtained for wholesale distribution activity and manufacturing activity.

(3) The licensee need not be under the supervision of a licensed pharmacist, but shall be under the supervision of a responsible officer or management employee.

(4) There has not been established minimum requirements for persons employed by persons engaged in the distribution or manufacture of prescription drugs; however, this does not relieve the person who engages in the distribution of prescription drugs within the state or in interstate commerce into or from the state, or those engaged in the manufacture of prescription drugs in the state or in interstate commerce into or from the state from ensuring that persons employed by them have appropriate education, experience, or both to engage in the duties to which they are assigned and do so in a manner which does not jeopardize the public health, safety or welfare.

(5) All facilities associated with the distribution or manufacture of prescription drugs shall:

(a) be of suitable size and construction to facilitate cleaning, maintenance and proper operations;

(b) have storage areas designed to provide adequate lighting, ventilation, sanitation, space, equipment and security conditions;

(c) have the ability to control temperature and humidity within tolerances required by all prescription drugs and prescription drug precursors handled or used in the distribution or manufacturing activities of the applicant or licensee;

(d) provide for a quarantine area for storage of prescription drugs and prescription drug precursors that are outdated, damaged, deteriorated, misbranded, adulterated, opened or unsealed containers that have once been appropriately sealed or closed, or in any other way unsuitable for use or entry into distribution or manufacture;

(e) be maintained in a clean and orderly condition, and

(f) be free from infestation by insects, rodents, birds, or vermin of any kind.

(6) In regard to security, all facilities used for wholesale drug distribution or manufacturing of prescription drugs shall:

(a) be secure from unauthorized entry;

(b) limit access from the outside to a minimum in conformance with local building and life/safety codes, and control access of persons to ensure unauthorized entry is not made;
(c) limit entry into areas where prescription drugs or prescription drug precursors are held to authorized persons who have a need to be in those areas;
(d) be well lighted on the outside perimeter;
(e) be equipped with an alarm system to permit detection of entry and notification to appropriate authorities at all times when the facility is not occupied for the purpose of engaging in distribution or manufacture of prescription drugs; and
(f) be equipped with security measures, systems and procedures necessary to provide reasonable security against theft and diversion of prescription drugs or alteration or tampering with computers and records pertaining to prescription drugs or prescription drug precursors.
(7) In regard to storage, all facilities shall provide for storage of prescription drugs and prescription drug precursors in accordance with the following:
(a) all prescription drugs and prescription drug precursors shall be stored at appropriate temperature, humidity and other conditions in accordance with labeling of such prescription drugs or prescription drug precursors or with requirements in the United States Pharmacopeia/National Formulary (USP/NF), [~~1995~~]2002 edition, which is official from January 1, 2003 through Supplement [~~4~~]2, dated August 1, [~~2001~~]2003, which is hereby incorporated by reference;
(b) if no storage requirements are established for a specific prescription drug or prescription drug precursor, the products shall be held in a condition of controlled temperature and humidity as defined in the USP/NF to ensure that its identity, strength, quality, and purity are not adversely affected; and
(c) there shall be established a system of manual, electromechanical or electronic recording of temperature and humidity in the areas in which prescription drugs or prescription drug precursors are held to permit review of the record and ensure that the products have not been subjected to conditions which are outside of established limits.
(8) In regard to examination of materials, each facility shall provide that:
(a) upon receipt, each outside shipping container containing prescription drugs or prescription drug precursors shall be visually examined for identity and to prevent the acceptance of prescription drugs or prescription drug precursors that are contaminated, reveal damage to the containers or are otherwise unfit for distribution; and
(b) each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
(9) In regard to returned, damaged, and outdated prescription drugs, each facility shall provide that:

(a) prescription drugs or prescription drug precursors that are outdated, damaged, deteriorated, misbranded, adulterated, or in any other way unfit for distribution or use in manufacturing shall be quarantined and physically separated from other prescription drugs or prescription drug precursors until they are appropriately destroyed or returned to their supplier;
(b) any prescription drug or prescription drug precursor whose immediate sealed or outer secondary sealed container has been opened or in any other way breached shall be identified as such and shall be quarantined and physically separated from other prescription drugs and prescription drug precursors until they are appropriately destroyed or returned to their supplier; and
(c) if the condition or circumstances surrounding the return of any prescription drug or prescription drug precursor cast any doubt on the product's safety, identity, strength, quality, or purity, then the drug shall be appropriately destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the product meets appropriate and applicable standards related to the product's safety, identity, strength, quality, and purity.
(10) In regard to record keeping, pharmaceutical wholesaler/distributors and pharmaceutical manufacturers shall establish and maintain records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and prescription drug precursors and shall make inventories of prescription drugs and prescription drug precursors and required records available for inspection by authorized representatives of the federal, state and local law enforcement agencies in accordance with the following:
(a) there shall be a record of the source of the prescription drugs or prescription drug precursors to include the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;
(b) there shall be a record of the identity and quantity of the prescription drug or prescription drug precursor received, manufactured, distributed or shipped, or otherwise disposed of by specific product and strength;
(c) there shall be a record of the dates of receipt and distribution or other disposal of any product;
(d) there shall be a record of the identity of persons to whom distribution is made to include name and principal address of the receiver, and the address of the location to which the products were shipped;
(e) inventories of prescription drugs and prescription drug precursors shall be made available during regular business hours to authorized representatives of federal, state and local law enforcement authorities;
(f) required records shall be made available for inspection during regular business hours to authorized representatives of federal, state and local law enforcement authorities, and such records shall be maintained for a period of two years following disposition of the products; and

(g) records that are maintained on site or immediately retrievable from computer or other electronic means shall be made readily available for authorized inspection during the retention period; or if records are stored at another location, they shall be made available within two working days after request by an authorized law enforcement authority during the two year period of retention.

(11) In regard to written policies and procedures, pharmaceutical wholesaler/distributors and pharmaceutical manufacturers shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, manufacture, distribution or other disposal of prescription drugs or prescription drug precursors, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. In addition, the policies shall include the following:

(a) a procedure whereby the oldest approved stock of a prescription drug or precursor product is distributed or used first, with a provision for deviation from the requirement if such deviation is temporary and appropriate;

(b) a procedure to be followed for handling recalls and withdrawals of prescription drugs adequate to deal with recalls and withdrawals due to:

(i) any action initiated at the request of the Food and Drug Administration of other federal, state or local law enforcement or other authorized administrative or regulatory agency;

(ii) any voluntary action by the pharmaceutical wholesaler/distributor or pharmaceutical manufacturer to remove defective or potentially defective drugs from the market; or

(iii) any action undertaken to promote public health, safety or welfare by replacing of existing product with an improved product or new package design;

(c) a procedure to ensure that a pharmaceutical wholesaler/distributor or pharmaceutical manufacturer prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state or national emergency;

(d) a procedure to ensure that any outdated prescription drugs or prescription drug precursors shall be segregated from other drugs or precursors and either returned to the manufacturer, other appropriate party or appropriately destroyed;

(e) a procedure providing for documentation of the disposition of outdated, adulterated or otherwise unsafe prescription drugs or prescription drug precursors and the maintenance of that documentation available for inspection by authorized federal, state, or local authorities for a period of two years after disposition of the product.

(12) In regard to responsible persons, pharmaceutical wholesaler/distributors and pharmaceutical manufacturers shall establish, maintain and make available for inspection by authorized federal, state and local law enforcement authorities, lists of all officers, directors,

managers, and other persons in charge of wholesale drug distribution, manufacture, storage, and handling, which lists shall include a description of their duties and a summary of their background and qualifications.

(13) In regard to compliance with law, pharmaceutical wholesalers/distributors and pharmaceutical manufacturers shall:

(a) operate in compliance with applicable federal, state and local laws and regulations;

(b) permit the state licensing authority and authorized federal, state, and local law enforcement officials, upon presentation of proper credentials, to enter and inspect their premises and delivery vehicles, and to audit their records and written operating policies and procedures, at reasonable times and in a reasonable manner, to the extent authorized by law; and

(c) obtain a controlled substance license from the division and register with the Drug Enforcement Administration (DEA) if they engage in distribution or manufacture of controlled substances, and shall comply with all federal, state and local regulations applicable to the distribution or manufacture of controlled substances.

(14) In regard to salvaging and processing, pharmaceutical wholesalers/distributors and pharmaceutical manufacturers shall be subject to and shall abide by applicable federal, state and local laws that relate to the salvaging or reprocessing of prescription drug products.

(15) A person who is engaged in the wholesale distribution or manufacturing of prescription drugs but does not have a facility located within Utah in which prescription drugs are located, stored, distributed or manufactured is exempt from Utah licensure as a pharmaceutical wholesaler/distributor or a pharmaceutical manufacturer, if said person is currently licensed and in good standing in each state of the United States in which that person has a facility engaged in distribution or manufacturing of prescription drugs entered into interstate commerce.

KEY: pharmacists, licensing, pharmacies
[~~November 15, 2001~~]2003
Notice of Continuation April 26, 2001

58-17a-101
58-37-1
58-1-106(1)(a)
58-1-202(1)(a)